

previously included in the claims be reference. Thus, the claims have been neither broadened nor narrowed by these amendments.

Rejection of claims 83-106, 108-113, 116-124, and 126-131 under 35 U.S.C. § 112, first paragraph

Claims 83-106, 108-113, 116-124, and 126-131 were rejected as non-enabled. The Office Action alleged that the specification fails to enable use of the claimed variants of Tbp2 because the variants encompassed within the scope of the claims would have unpredictable tertiary structure, resulting in uncertainty in the functionality and effect on the ability of antibodies to recognize the variant Tbp2. For the following reasons, the applicants respectfully disagree.

The applicants respectfully note that the burden is on the Patent Office to establish that the specification is non-enabling, and "whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." *In re Marzocchi*, 439 F.2d 220, 223, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971). The applicants respectfully submit that the Office Action's reasoning in support of this rejection is in conflict with the empirical evidence presented in the specification and, therefore, insufficient to support of allegation of non-enablement.

Examples 12 and 13 demonstrate that polypeptides according to the invention in which substantial portions or essentially all of the second and third domains of Tpb2 have been deleted are capable of eliciting bactericidal antibodies against several strains of *N. meningitidis*. The success with these constructs, in which up to nearly half of the native protein has been deleted, demonstrates that even substantial deletions result in immunogenic polypeptides and, thus, the

concerns expressed in the Office Action are not only mere speculative, but inconsistent with empirical evidence. Consequently, the basis for this rejection is insufficient to satisfy the Patent Office's burden of establishing non-enablement.

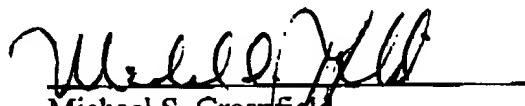
Furthermore, many of the pending claims encompass polypeptides either having fewer deletions to the native Tbp2 protein than those tested in Example 12 and 13 and/or similar deletions. Example 12 demonstrates that the polypeptide resulting from deletion of amino acids 351-691 of *N. meningitidis* strain IM2169 Tbp2 is effective. Example 13 demonstrates that the polypeptide resulting from deletion of amino acids 362-379, 418-444, 465-481, and 500-520 of *N. meningitidis* strain IM2169 Tbp2 is effective. Claims 96, 102, 107-131 (at least) all recite polypeptides bearing substantial similarity to the polypeptides demonstrated to be effective in Examples 12 and 13.

In summary, in view of the fact that the Office Action's basis for rejecting the claims as non-enabled is in conflict with the empirical evidence, the applicants respectfully request reconsideration and withdrawal of this § 112, first paragraph, rejection.

If there are any questions or comments regarding this Response or application, the Examiner is encouraged to contact the undersigned attorney as indicated below.

Respectfully submitted,

Date: April 3, 2001


Michael S. Greenfield
Registration No. 37,142

Telephone: 312-913-0001
Facsimile: 312-913-0002

McDonnell Boehnen Hulbert & Berghoff
300 South Wacker Drive
Chicago, IL 60606